Elliot C. Semet-Inventor, Interlocking IM Nails with Threaded Guidewire
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A. APPLICATION DATA SHEET: Not Applicable

B. SPECIFICATION:

An Intramedullary Nail (IM Nail) is inserted into the cortical bone. The IM Nail is secured by screws and threaded guidewire; this will secure and eliminate movement of the screws to the IM Nail. The IM Nail will have a guidewire track through the inside that connects each of the screw openings. Upon insertion of the first most distal screw that will be locked to the nail is placed, a threaded guidewire is inserted through the slot of the Intramedullary Nail. The more proximal screw will exert a force that pushes the threaded guidewire into the more distal screw and cause the guidewire and distal screw threads to interlock. The exerted force of the more proximal screw is caused by the length of the threaded guidewire. When the proximal screw is tightened, it pushes the guidewire down further to the distal screw causing a secure or interlocking connection. The distal screw may or may not be further secured by tightening/turning of the proximal screw such that it further pulls the guidewire around the distal screw aiding in locking.

The interlocking may occur due to the pressure of the guidewire, wrapping of the guidewire around one or both of the screws, through perforations within the screw, or other means that results in interlocking. There may be alternative means of pushing the threaded guidewire into or around the more distal screw and causing interlocking. Direct manual pressure applied on the guidewire may cause the guidewire to break as the proximal screw is inserted; or an alternative mechanism may push the threaded guidewire into the more distal screw and cause them to interlock. Additionally, the guidewire may be curved on the bottom or have a y shape in order to aid locking around the most distal screw.

The screw may also be designed such that it is tapered and has segmented, partial or full threading. The tapering would ensure the initial threads on the tip pass through the guidewire without early gripping. The middle threads would engage the guidewire and the IM Nail. The wider end of the screw would eliminate movement of one end of the screw, while the other end will rely on the guidewire to eliminate play.

This process is repeated for additional screw sets so that the most proximal screw will always lock in the previous screw placed in. The final screw can be locked with an end cap that has a

threaded tip that can exert more pressure on the most proximal screw. This method can be used in conjunction with other locking mechanisms.

C. TITLE OF INVENTION:

A new method of locking Intramedullary Nails is to use threaded guidewire. The threaded guidewire is placed in between screws of an intramedullary nail. Whenever a more proximal screw is placed with the guidewire, the more distal screw is locked to the nail. In addition, movement or play of the more proximal screw is minimized. This new design including both the guidewire and screw locks the screw in place to eliminate this play and result in a more stable form of fixation.

D. CROSS REFERENCE TO RELATED APPLICATIONS:

Provisional Patent Application #: 60/459,953 with a filing date of April 4, 2003 (submitted by inventor of this application).

Patent #6,019,761, dated February 1, 2000 suggests interlocking by using guidewire that goes in through the IM Nail holes, up or down the IM Nail and out the next hole.

Patent #6,524,314, dated February 25, 2003 suggests interlocking by using 2 lag screws and a locking screw through the IM Nail.

E. STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT: Not Applicable

F. REFERENCE TO SEQUENCE LISTING: Not Applicable

G. BACKGROUND OF THE INVENTION:

The current methods of fracture reduction are:

- Casts / braces
- Plates:
    - Conventional

    - Locking
- External fixation
- Intramedullary Nails

Intramedullary Nails have several advantages over other forms of fixation:

- they are less invasive than plates;
- they have a lower infection rate;
- nails are stronger than the plates;
- nails have a mechanical advantage compared to plates;
- the screws used with nails are more resistant to breakage due to the decreased moment arm;
- screws may be placed in different planes;
- nails have a high rate of union;
- nails allow for anatomic reduction;
- cast/braces immobilize the limb and do not allow early motion;
- external fixators have a risk of pin tract infections.

One of the current method of interlocking IM Nails is to solely use screws, which can result in loss of reduction because of the inherent play in screw-nail interface. A second way of interlocking IM Nails is to cap the screw at the contra lateral cortex, which increases fixation in the cortical bone; however, does not help the screw-nail interface; additionally, pressure applied by the capping on one end may cause the distal end to move out of position. A third available way of interlocking IM Nails is to have the hole of the IM Nail lined with rubber to provide a more grippable material for the screws; however, the inherent play in rubber does not provide sufficient locking. The rubber line IM Nails also have the possible for foreign body reactions with flaking of the rubber.

This new mechanism, with threaded guidewire in between the screws, locks the screw in place to eliminate this play and result in a more stable form of fixation.

Two other patented ways of interlocking IM Nails were found, however, neither are currently marketed:

- An interlocking Intramedullary Nail (patent #6,524,314, granted February 25, 2003) provides for a different mechanism, using 2 lag screws and a locking screw. This product is currently not marketed; however, this would be a difficult mechanism because there are only a couple of safe zones where screws can be placed. With the addition of 2 screws placed for fixation, it may be difficult to find safe zones. Additionally, the may cross thread early prohibiting further insertion.
- An interlocking Intramedullary Nail (patent #6,019,761, granted February 1, 2000) provides for interlocking by placing a guidewire through one screw hole up to and out of the next. This patent also relies on drilling holes versus already manufactured holes and dropping wires through the holes and using the screws to cause the wires to interlock to the screws. This patent has a complete different means by which the interlocking would occur and be enhanced.

H. BRIEF SUMMARY OF THE INVENTION:

This invention provides for a new method for locking Intramedullary Nails (IM Nails) with Threaded Guidewire. The current methods of interlocking screws has inherent play in the screw-nail interface and therefore can result in loss of reduction. This new design uses screws to begin locking the IM Nail, followed by using threaded guidewire that is placed in between screws of the IM Nail. Whenever a more proximal screw is placed with the threaded guidewire, it causes the guidewire to push/lock onto or around the distal screw eliminating the play and causing a more stable form of fixation.

The screws may be tapered and may be partially, segmented or fully threaded. The tapering and threading would allow for maximum screw strength, a lag effect, centering of the IM Nail and fixation to the nail.

I. BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING:

1. Page 1: Diagram of showing the first, distal screw placement and guidewire track
    1.Cortical Bone
    2.Guidewire Track
    3.First locking screw inserted
    4.Intramedullary Nail

2. Page 2: Diagram of placement of threaded guidewire through guidewire track to first distal screw.
    1.Threaded guidewire
    2.Guidewire track opening for placement of guidewire
    3.Threaded guidewire against first distal screw
    4.First distal screw
3. Page 3: Diagram of all screws and guidewire placed between each screw; each screw is secured by the guidewire force onto the screw or wrapping around the screw
    1.First distal screw
    2.Second screw (proximal to first distal, distal to third screw)
    3.Third screw
    4.Fourth screw
    5.Cortical bone
    6.Intramedullary Nail
    7.Threaded guidewire placed between all screws
4. Page 4: Diagram of side view of how the guidewire wraps or pushes against the threads of the placed screws.
    1.Joint of guidewire and screw
    2.Design of an alternative tapered screw that has segmented threads for maximum interlocking.
    3.The widest end of screw has large threads to grip to the bone
    4.The middle threads are finer to engage the guidewire

5.The tapered end threads are larger to grip bone; however, the tapered end allows guidewire to pass by the guidewire to eliminate early locking/gripping.

J. DETAILED DESCRIPTION OF THE INVENTION:

The IM Nails and screws are manufactured with cobalt-chrome, titanium, stainless steel or other materials for strength and durability and body compatibility. The threaded guidewire is manufactured from the same materials.

The combination of the screws and threaded guidewire eliminates play in the fixation to maintain reduction. The current methods do not address screw-nail interface locking. and can cause loss in reduction.

After insertion of the Intramedullary Nail (IM Nail) into the cortical bone, the first, most distal screw is placed. A threaded guidewire is place down the inside of the IM Nail through a guidewire track. The placement of the next, proximal screw pushes the guidewire into, onto or around the first distal screw causes a stable interlock. The distal screw may or may not be further secured by tightening/turning of the proximal screw such that it further pulls the guidewire around the distal screw aiding in locking.

The interlocking may occur due to the pressure of the guidewire, wrapping of the guidewire around one or both of the screws, or other means that results in interlocking. There may be alternative means of pushing the threaded guidewire into or around the more distal screw and causing interlocking. Direct manual pressure applied on the guidewire may cause the guidewire to break as the proximal screw is inserted; or alternative mechanism that will push the threaded guidewire into the more distal screw and cause them to interlock. Additionally, the guidewire may be curved on the bottom or have a y shape in order to aid locking around the most distal screw.

The screw may also be designed such that it is tapered and has segmented, partial or full threading. The tapering would ensure the initial threads on the tip pass through the guidewire without early gripping. The middle threads would engage the guidewire and the IM Nail. The wider end of the screw would eliminate movement of one end of the screw, while the other end will rely on the guidewire to eliminate play.

This process is repeated for additional screw sets so that the most proximal screw will always lock in the previous screw placed in. The final screw can be locked with an end cap that has a

threaded tip that can exert more pressure on the most proximal screw. This method can be used in conjunction with other locking mechanisms.

This invention will provide for the most stable reduction that maintains the advantages over the current and alternative means of reducing fractures.